AWARD NUMBER: W81XWH-15-1-0522

TITLE: Determining Clinically Relevant Changes in Community
Walking Metrics to Be Tracked by the VA as Part of Routine Care
in Lower Limb Amputee Veterans

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                          Fort Detrick, Maryland 21702-5012

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Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT
The objective of this study is to define clinically meaningful change in the walking function of lower limb prosthetic users in order to more easily assess whether a patient is improving or declining in function over time. However, little is known about the natural fluctuations in walking metrics from week to week when walking function is stable versus clinically relevant changes in walking function. Therefore, it will be important to define meaningful change in walking function when interpreting the impact of prosthetic components, rehabilitation, and other treatments on real world walking.

Recruitment and data collection is on track in this study. A total of 52 subjects have enrolled in the study: Veteran subjects n=34 and University of Utah subjects n=18. Preliminary analysis indicates that daily steps and distance walked may track most closely to perceived change in walking function. However, data collection is on-going and necessary before cut points that represent meaningful change is recommended.

15. SUBJECT TERMS
walking, ambulation, lower limb prosthesis, function, clinically relevant change

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT	b. ABSTRACT	c. THIS PAGE	Unclassified	8	19b. TELEPHONE NUMBER *(include area code)*
Unclassified	Unclassified	Unclassified			

Table of Contents

INTRODUCTION

The objective of this study is to determine clinically meaningful change in the community walking metrics to be tracked by the VA as part of the new VA initiative. The metrics are the following: 1) functional level assessment, 2) peak performance index, 3) daily steps, 4) walking distance, 5) cadence, and 6) cadence variability. The specific aims are 1) to determine small meaningful change in the community metrics and 2) to determine substantial meaningful change in the community metrics. The sensitivity and specificity of each cut-point value representing small and substantial change will also be reported.

This study will require the recruitment of 100 research participants that ambulate with a lower limb prosthesis. Participants will be recruited from the Salt Lake City VA Medical Center and the University of Utah amputee clinic. The StepWatch activity monitor will be attached to the prosthesis and provide weekly reports on the participant's community walking metrics. Clinically relevant change will be based on participant reported Global Mobility Change Rating score for each week. Each participant will be monitored for six months. A diagnostic testing framework will be used to find the optimal cut-points on the community metrics, which maximizes classification accuracy (no change, small meaningful change, or substantial meaningful change).

KEYWORDS

Ambulation, walking, function, lower limb prosthesis, veteran, clinically relevant change

ACCOMPLISHMENTS

What were the major goals of the project?

Specific Aims: 1) to determine small and 2) substantial meaningful change in the community walking metrics	Timeline	Status
Major Task 1: Human Subject Research Approval	Months	
Milestone #1: Achieve IRB and USAMRMC ORP HRPO Approval	3	Completed
Major Task 2: Data Collection		
Milestone #2: Complete data collection (n=100)	22	52% Completed
Major Task 3: Data Analysis		
Milestone #3: Complete Data Analysis	23	20% Completed
Major Task 4: Reporting / Data Sharing		
Milestone #4: Reporting requirements and data sharing protocols completed	24	20% Completed

What was accomplished under these goals?

Human subject approvals were obtained and data has been collected on 52 out of the target 100 subjects. This is recruiting at a rate of 1.67 subjects a week. Activities included recruiting and consenting 52 subjects, programming StepWatches, placing StepWatches on prostheses, collection of weekly Global Mobility Change Rating scores, mailing StepWatches weekly, and receiving / downloading Stepwatches weekly. In addition, Dr. Chou has reviewed 139 weeks of data and processed the walking metrics for each of these weeks. In coordination with the statistician, a preliminary analysis was performed. The metrics with the strongest correlation to the Global Mobility Change Rating score was change in daily steps ($p=0.008$) and change in daily distance walked ($p=0.030$). Change in cadence, cadence variability, peak performance index, and functional level indices did not correlate to the Global Mobility Change Rating score at this time. Optional cut-points will be established once data collection and processing is complete.

What opportunities for training and professional development have the project provided?

This project has included two medical residents training in the rehabilitation field. They are assisting in the data processing of the walking metrics and have contributed to the development of a research abstract submitted to the Association of Academic Physiatrists. They are receiving value research and technical writing experience.

How were the results disseminated to communities of interest?

An abstract was submitted to the Association of Academic Physiatrist with preliminary results. If awarded a presentation, more information about our study and its results will reach clinical professionals in the field of physical medicine and rehabilitation.

What do you plan to do during the next reporting period to accomplish the goals?

During the next reporting period, I intend to complete data collection, data processing, and data analysis. A manuscript will be prepared for submission of this study and results will be posted on our website.

IMPACT

What was the impact on the development of the principal discipline(s) of the project?

The project is creating a data rich dataset that can be used to address other research questions. For example, new community walking metrics can be created and analyzed using the files already collected on subjects. This allows further learning without the expense of recruiting new subjects. The assessment of new walking metrics without the need of additional human subject data collection was leveraged in a new DoD Outcomes Research grant submission.

What was the impact on other disciplines?

Nothing to report

What was the impact on technology transfer?

Nothing to report

What was the impact on society beyond science and technology?

Nothing to report

CHANGES/PROBLEMS

Changes in approach and reasons for change

Nothing to report

Actual or anticipated problems or delays and actions or plans to resolve them

Nothing to report

Changes that had a significant impact on expenditures

Nothing to report

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Nothing to report

PRODUCTS

Nothing to report

PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

Provide the name and identify the role the person played in the project

Name	Project Role	Research Identifier	Person month worked	Contribution to project	Funding support
Teri Chou, PhD	PI	0000-0001-8401-2938	4	Overview of project, data processing, patient recruitment, statistical	N/A

				overview	
Bradeigh Godfrey, DO	Subcontract PI (WIBR at the SLC VA Hospital)	N/A	1	Patient recruitment, data download, mailing stepwatches, recruitment of medical residents	N/A
Jacob Smith, MS	Study coordinator	N/A	3	Interfacing with IRB, patient recruitment, weekly subject survey calls, overseeing mailing of stepwatches, and subject payment.	N/A

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Nothing to Report

What other organizations were involved as partners?

Nothing to Report

SPECIAL REPORTING REQUIREMENTS

The Quad Chart is in the appendix

APPENDICES

Determining clinically relevant changes in community walking metrics to be tracked by the VA as part of routine care in lower limb amputee veterans

Log No: OP140008

PI: Teri Chou, PhD   **Org:** Modus Health LLC   **Award Amount:** $465,470
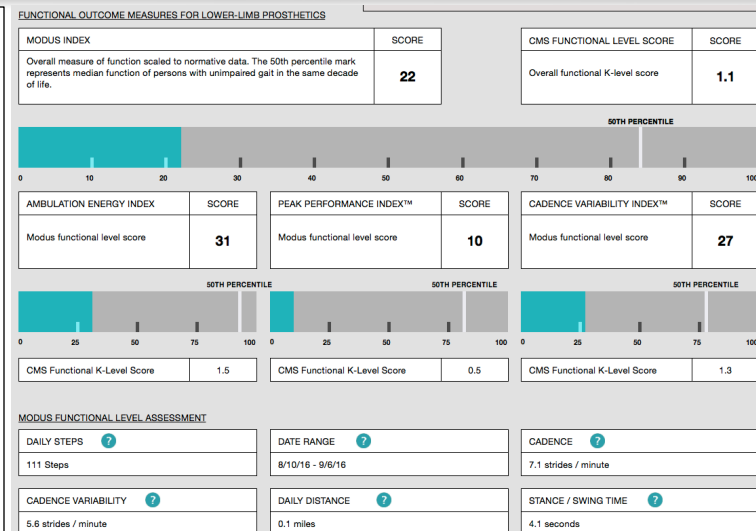
Study/Product Aim(s)

• To determine the magnitude of clinically relevant change in the community walking metrics to be tracked by the VA in veteran lower limb prosthetic users.

Approach

A sample size of n=100 Veteran and University of Utah patients that use lower limb prostheses will be recruited. Each participant will receive a StepWatch on their prosthetic limb for tracking community metrics for six months (Figure 1). An email or phone survey will be used for collecting weekly responses to the Global Mobility Change Rating scale for determining small and substantial meaningful change. Data will be analyzed to determine each metrics small and substantial change thresholds and the associated sensitivity and specificity for these thresholds.

Figure 1 – Depicts subject 46's first month of walking metrics.

Recruited n=52 participants. At least 1 month of walking data on n=46.

Timeline and Cost

Activities	CY	15/16	16	16/17	17
IRB Approval					
Data Collection					
Analyze Results					
Reporting / Data Sharing					
Estimated Budget ($465K)			**$276K**		**$189K**

Updated: 06/28/2016

Goals/Milestones

CY15 Goal – IRB Approval
☑ Prepare/Submit IRB application
☑ Obtain IRB approval
☑ Obtain HRPO regulatory approval

CY16 Goal – Recruitment and Data Collection
☐ Recruit/Collect Data n=80 subjects

CY17 Goal – Recruitment, Data Collection, Analyze Results, Reporting, Data Sharing
☐ Complete recruitment and data collection on n=100 subjects
☐ Complete data entry and data cleaning procedures
☐ Complete statistical analysis
☐ Provide Quarterly reports to USAMRAA
☐ Share data results on Modus Health LLC website
☐ Prepare manuscript for JRRD submission

Comments/Challenges/Issues/Concerns
None

Budget Expenditure to Date
Projected Expenditure: $276K   Actual Expenditure: $146K